

PATENT NON-FINAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Kazuhisa MATSUDA

Serial Number: 09/489,473

Filed: January 21, 2000

For: SUTURABLE ADHESION-PREVENTING MEMBRANE

RESPONSE UNDER 37 C.F.R. § 1.111
TO THE OFFICE ACTION DATED NOVEMBER 6, 2002

Assistant Commissioner for Patents Washington, D.C. 20231

April 7, 2003

Group Art Unit:

Examiner: C. C. Pratt

Sir:

This paper is submitted in response to the Office Action dated November 6, 2002. A petition for a two-month extension of the period for responding to the Action is being filed concurrently herewith.

In the Action, claims 1-33 are rejected under 35 U.S.C. § 103(a) over Light et al. (U.S. Patent No. 5,514,181) ("Light") in

P:\04-03\niss-049-111.wpd

view of Silver et al. (U.S. Patent No. 5,171,273) ("Silver").

Reconsideration and removal of this rejection are respectfully requested.

In response to the prior actions in this application, in which the Office relied on Light alone as supporting a rejection of the claims under 35 U.S.C. § 103(a), applicant argued that the prosthesis of Light is in the form of a multilayered spiral roll comprising a foraminous layer that is required to be a synthetic bioabsorbable material. In the present Action, the Office avoids this issue by relying on Silver. Silver describes replacement parts made of synthetic collagen fibers. The position of the Office is that it would have been obvious to one of ordinary skill in the art at the time the present invention was made to use the synthetic collagen fibers of Light to form the nonwoven foraminous layer of Light.

Applicant respectfully submits that the combination of Light and Silver does not provide the motive required under 35 U.S.C. § 103(a) to modify the absorbable prosthesis of Light as proposed by

the Office when the "Background of the Invention" described in Light is considered. In the "Background of the Invention" section (Col. 1, lines 58-67) Light describes Silver as disclosing absorbable ligament or tendon prostheses formed from high-strength collagen fibers that are obtained by cross-linking reconstituted collagen fibers. In the paragraph preceding the description of Silver, WO85/00511 is described as disclosing a collagen-based material for regeneration of ligaments and/or tendons. The material is described as being formed from strands of collagen that have been cross-linked with glutaraldehyde to increase their tensile strength.

However, Light then describes the drawback of this prior art as follows:

"A drawback of tendon and/or ligament prostheses that are formed solely from collagen is that the collagen loses its tensile strength in vivo, even when cross-linked <u>as described above</u>. This characteristic of collagen is incompatible with the relatively long healing times required for repair of ligaments or tendons."

(Col. 2, lines 1-6). (Emphasis added). When this disclosure is considered, it is seen that the motivation alleged in the Action

for a person of ordinary skill in the art to use the synthetic collagen fibers of Silver to form the nonwoven layer of Light, i.e., "the desire to obtain high-strength combined with beneficial wound healing properties" (Action, page 3, lines 6-7), does not exist.

Moreover, the invention of Light was made with obvious knowledge of the Silver patent. If Light believed the collagen fibers of Silver would not exhibit the drawback described in the patent when used in the Light prosthesis, Light would have described such fibers as being useful. The fact that Light does not disclose the collagen fibers of Silver as being useful for the foraminous layer is further evidence supporting the lack of proper motivation to modify Light with Silver as proposed in the Action.

For these reasons alone, the combination of Light and Silver cannot support a case of prima facie obviousness of claims 1-33 and removal of the 35 U.S.C. § 103(a) rejection is in order.

Furthermore, the invention recited in the claims of the present application is a membrane. Light does not disclose a

membrane, but instead discloses a prosthesis in the form of a multilayered spiral roll. The laminate of a foraminous layer of bioabsorbable material, bioabsorbable film and aqueous gel (Col. 4, lines 47-52) used to prepare the prosthesis of Light is not disclosed as having any utility other than as a raw material for the prosthesis of Light. Moreover, this laminate is not within the scope of the claims of the application because the aqueous gel is not converted into a sponge layer until after the laminate is rolled up into a spiral roll.

Removal of the 35 U.S.C. § 103(a) rejection is in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated November 6, 2002, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicant hereby petitions for an appropriate extension of

time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK

Ronald . Kubovcik

Reg. No. 25,401

Atty. Case No. NISS-049 The Farragut Building Suite 710 900 17th Street, N.W. Washington, D.C. 20006 Tel: (202) 887-9023

Fax: (202) 887-9093

RJK/cfm